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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,372	03/12/2004	Jeffrey S. Mumm	15060-58	7301

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PATRICK W. RASCHE (15060)  
ARMSTRONG TEASDALE, LLP  
ONE METROPOLITAN SQUARE  
SUITE 2600  
SAINT LOUIS, MO 63102-2740

EXAMINER
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BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

NOTIFICATION DATE	DELIVERY MODE
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07/16/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent@otm.wustl.edu  
USpatents@armstrongteasdale.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/799,372	<b>Applicant(s)</b> MUMM ET AL.	
	<b>Examiner</b> Valarie Bertoglio	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 31,33,34,36 and 43-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31,33,34,36,43,45,46 and 48 is/are allowed.
- 6) ☐ Claim(s) 44,47,49 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03/12/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's reply filed on 04/11/2008 has been entered.

Claims 1-30,32,35,37-42 and 51 are cancelled.31,36,43-50 are amended. Claims 31,33-34,36 and 43-50 are pending and under consideration in the instant office action.

#### ***Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44,47 and 50 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". The rejection is maintained for reasons of record set forth at page 3 of the office action dated 011/11/2008.

Claims 44,47 and 50 lack written description because in the instant case the glial, pancreatic and kidney specific expression is not supported by the specification. Applicant is claiming a fish wherein the critical element of the invention is the expression in a specific subset of cells of the fish. The specification contemplates tissue or cell-type specific expression including heart, muscle, neural, skeletal and cartilaginous tissues. The specification fails to contemplate, however, expression in glial cells, pancreas, or kidney.

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Applicant's arguments have been fully considered and are not persuasive. Applicant argues that the specification supports use of tissue specific expression, namely that of the nervous system and the enteric system. Applicant submits Exhibit A discussing that glial cells are part of the nervous system and Exhibit B, discussing that the pancreas is part of the enteric system. This argument is not persuasive in that the specification fails to support the species of glial-specific, pancreas-specific and kidney-specific promoters. "Neural-specific" and "enteric-specific" as recited in the specification do not lend descriptive support to "glial-specific", "pancreas-specific" and "kidney-specific" promoters or gene expression. In the instant case, the description of a genus is not sufficient to lend support for each potential species. Furthermore, Exhibit B is relevant to the "Enteric Endocrine System". The term "enteric" is regarded, in the art, as referring to the intestines. The pancreas is a gland of the endocrine system that affects digestion.

The rejection of claims 48-51 regarding use of the terminology "in cis" and "in trans" in claims 48 and 51 is withdrawn

#### *Scope of enablement*

Claims 49-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed transgenic fish wherein, in the presence of GAL4, the gene product is expressed as claimed, does not reasonably provide enablement for expression of the gene in the absence of the GAL4 transcriptional activator. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

This rejection is necessitated by the amendment to claim 48.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening.

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However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 48-50 are drawn to an aspect of the invention wherein the transgene encoding an ablation promoting moiety is not operably linked to a tissue specific promoter but is linked to a minimal promoter and a UAS, an enhancer sequence that is activated to cause expression from the minimal promoter by the GAL4 transcriptional activator. Claim 48, as amended, no longer requires the presence of a transcriptional activator and is drawn only to a fish comprising the "UAS" effector transgene. Claims 49 and 50 are limited to the claimed 'UAS' fish and require that the transgene be expressed in particular cells.

Desired expression of a "UAS" construct does not occur in the absence of the driver GAL4, which is introduced to the fish as by a driver transgene comprising GAL4 operably linked to a desired tissue-specific promoter. The claims, however, encompass expression of the effector transgene in the absence of GAL4. The specification teaches expression of a transgene comprising a gene operably linked to a UAS and minimal promoter in the presence of GAL4 expression. However, the specification does not teach such expression in the absence of GAL4 expression. One cannot obtain the claimed fish without the

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cell-specific expression of GAL4. The claims, therefore, should require the presence of appropriate GAL4 expression to drive expression of the "UAS" construct as claimed.

Claim 48 does not require expression of the transgene and is not included in this rejection.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection of claims 35,37 and 41-42 under 35 USC 112, 2<sup>nd</sup> paragraph is withdrawn in light of Applicant's cancellation of the claims.

The rejection of claims 31,33-34,36,43-51 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicant's amendments to the claims.

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***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Valarie Bertoglio, Ph.D./  
Primary Examiner  
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